Comments by Corwin Zigler* at the U.S. Environmental Protection Agency Chartered Clean Air Scientific Advisory Committee (CASAC) Public Teleconference on Particulate Matter

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* Corwin Zigler, Ph.D., Associate Professor of Statistics and Data Sciences, University of Texas at Austin and Dell Medical School

I am an associate professor of statistics and data sciences at the University of Texas at Austin, specializing in the development and application of statistical and epidemiological methods for causal inference, focusing in particular on evaluating the health impacts of air pollution policies and exposures. With the weight of my expertise in causal inference methods, I wish to state my support for the framework of causal determination used in the current draft and previous ISAs. This framework for synthesizing broad swaths of evidence towards a comprehensive "weight of evidence" scientific judgment has been outlined, vetted, and used with success in the past, and I believe this framework is both useful for informing policy decisions and generally understood by most intended users of the draft ISA. While some members of CASAC appear to agree, other members appear intent on generating confusion about this framework, in part by wielding a smattering of technical elements drawn from across a wide range of scientific contexts, some of which bear only nominal relevance to the issues at hand in the draft ISA.

It is true that there is a rich tradition of causal inference methods grown from many corners of scientific inquiry, and that explicit causal methodology has spread into air pollution epidemiology relatively recently. Continuing to develop such methodology in studies of air pollution is most definitely worthwhile. However, the existence of a vast literature on causal inference methods does not preclude the usefulness of the ISA framework for making causal determinations in this context. While most literature on causal inference methods pertains to the analysis of individual studies, such a goal is distinct from the causal determinations of the ISA that are anchored to the synthesis of evidence across many diverse studies. Terms and concepts emanating from the analysis of individual studies cannot be universally applied to discredit a "weight of evidence" approach and, in fact, the ISA framework is consistent with much of the most relevant literature on causal inference methodology. Merely outlining the various challenges and uncertainties inherent to this task of inferring causality should not be regarded as an adequate indictment of the current ISA approach.

Translating the scientific principles of causality from their roots in controlled experiments to the realities of observational population-based studies is a large part of the disciplines of epidemiology and statistics - two areas where CASAC specifically lacks relevant expertise. In fact, I dispute the claims made in CASAC's draft report that the ISA does not "follow widely accepted scientific methods for deriving sound....scientific conclusions from available data," and seriously question whether any member of the current chartered

CASAC is qualified to accurately judge what would constitute "wide acceptance" when it comes to judgments of causality from observational population-based studies. Thus, I echo others' recommendation to reconvene a PM review panel and to include expertise that is glaringly lacking in the current chartered CASAC. If methods for causal inference with observational data are to continue at the fore of the discussion, then it is essential to include scientists expert in causal inference methodology - not just the technical window dressings of this rich literature, but expert in their application and interpretation amid the inherent challenges and uncertainties of population-based epidemiological research. The chartered CASAC has no such expert.